



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,687	07/31/2003	Phillip Mark Hogarth	5644AR-2-1	2688
22442	7590	11/28/2007		
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/632,687

Applicant(s)

HOGARTH ET AL.

Examiner

MISOOK YU

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2007 and 15 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-74 and 76-96 is/are pending in the application.
- 4a) Of the above claim(s) 67-73, 76, 80 and 82-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74, 77-79, 81, 95, and 96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 9/12/2007 and 8/15/2007 has been entered.

Claims 67-73, 76, 80 and 82-94 are withdrawn for reason of record.

Claims 67-74 and 76-96 are pending, and claims 74, 77-79, 81, 95, and 96 are examined on merits.

### ***Claim Rejections - 35 USC § 102, Withdrawn***

The rejection of claims 74, 77-79, and 81 under 35 U.S.C. 102(b) as being anticipated by Peltz et al., of record is withdrawn because the amended claims are no longer anticipated.

### ***Claim Rejections - 35 USC § 103***

Claims 74, 77-79, 81, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peltz et al., (cited above) in view of Yeh et al., Proc. Natl. Acad. Sci. 1992 Mar 1;89(5):1904-8.

Claim 74, 77-79, 81, 95, and 96 are interpreted as drawn to a polypeptide comprising an extracellular region of a native FcγRII receptor linked to human serum albumin (HSA).

Applicant argues that a reasonable expectation of success producing a biologically active fusion protein comprising Fc $\gamma$ RII and HAS is not expected because HAS is a big molecule and Fc $\gamma$ RII and CD4 are dissimilar.

This argument has been fully considered but found unpersuasive. As stated above, Peltz et al., teach a polypeptide comprising an extracellular region of a native Fc $\gamma$ RII receptor. Peltz et al., do not teach HSA. However, Yet et al., teach HSA has remarkably long half-life, together with its wide in vivo distribution and its lack of enzymatic or immunological functions” and therefore “fusion of bioactive peptides to HAS is a plausible approach toward the design and recovery” of secreted therapeutic.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings of Peltz et al., and Yeh et al., to arrive at the fusion of soluble Fc $\gamma$ RII linked to HSA as taught by Yeh et al., with a reasonable expectation of success to make a fusion protein, given the high skill in the recombinant DNA technology of making a fusion protein as disclosed by Yeh et al. One of ordinary skill would have been motivated to make the claimed fusion protein given the advantage of the fusion protein as stated in Yeh et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74, 77-79, 81, 95, and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-61 of U.S. Patent No. 5,985,599 in view of Yeh et al., (above). The patented claims are drawn to species (several SEQ ID Nos) of "an extracellular region of a native FcγRII receptor". The patented claims do not recite the fusion partner. However, Yeh et al., teach HSA has remarkably long half-life, together with its wide in vivo distribution and its lack of enzymatic or immunological functions" and therefore "fusion of bioactive peptides to HAS is a plausible approach toward the design and recovery" of secreted therapeutic.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings of Peltz et al., and Yeh et al., to arrive at the fusion of soluble FcγRII linked to HSA as taught by Yeh et al., with a reasonable expectation of success to make a fusion protein, given the high skill in the recombinant DNA technology of making a

fusion protein as disclosed by Yeh et al. One of ordinary skill would have been motivated to make the claimed fusion protein given the advantage of the fusion protein as stated in Yeh et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:  
10/632,687  
Art Unit: 1642

Page 6

MISOOK YU  
Primary Examiner  
Art Unit 1642

/Misook Yu/